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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,277	10/20/2003	Eddie F. Ray III	MSDI-269/PC545.02	2922
52196 7590 06/13/2008 KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 06/13/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/689,277

**Applicant(s)**

RAY ET AL.

**Examiner**

JERRY CUMBERLEDGE

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8-19, 27-32 and 34-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-19, 27-32 and 34-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-32, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US Pat. 5,505,732).

Michelson discloses a spinal instrument assembly comprising: a guide sleeve housing (Fig. 7F, ref. 340) including a proximal portion (Fig. 7F, near ref. 352) and a distal portion (Fig 7F, near ref. 344), said proximal portion including an inner wall defining a proximal chamber (Fig. 7F, wall surrounding ref. 100 and 348), said housing further including a first working channel port (Fig. 7F, portion where ref. 102, left, is received) and a second working channel port extending through said distal portion (Fig. 7F, portion where ref. 102, right, is received) and extending distally from and forming an extension of said proximal chamber (Fig. 7F), wherein said first and second working channel ports are in communication with one another through said distal portion (Fig. 7F) to; and a central distractor (Fig. 7F, ref. 102) in said chamber of said guide sleeve housing, said central distractor including a distractor tip movably positionable from a location between said first and second working channel ports (Fig. 7F), said distractor tip including upper and lower distraction surfaces defining a distraction height therebetween to maintain distraction of a spinal disc space (Fig. 7A, Fig. 7F). The

proximal chamber is sized to receive a distal end of a guide sleeve (Fig. 7F). The tip of said central distractor is centrally located in said housing (Fig. 7F). The central distractor is rotatable from a reduced height configuration whereby said upper and lower distraction surfaces are oriented away from vertebral endplates of a spinal disc space to a distraction configuration whereby said upper and lower distraction surfaces are oriented toward vertebral endplates of the spinal disc space (Fig. 7F, Fig. 7A). The instrument further comprising a housing inserter (Fig. 5, ref. 162) including a distal engaging portion (Fig. 5, near ref. 160) and a handle (Fig. 5, proximal portion of the device) extending proximally from said distal engaging portion (Fig. 5) and wherein said guide sleevehousing is removably engageable to said distal engaging portion of said housing inserter (Fig. 5). The central distractor includes a shaft extending proximally from said distractor tip (Fig. 7F, ref. 100). The housing inserter includes a passageway opening at a proximal end of said handle (Fig. 5, ref. 168) and at a distally oriented face of said engaging portion (Fig. 5), and wherein said shaft of said central distractor is sized for receipt in said passageway so that said housing inserter and said guide sleeve housing are movable along said shaft toward said distractor tip to position said guide sleeve housing in said operative position (Fig. 5, Fig. 7F). The proximal portion of said guide sleeve housing defines a groove formed in said inner wall that defines said proximal chamber (Fig. 7F, since the inner wall is curved it forms a groove). The central distractor includes a housing engaging portion (Fig. 7F, ref. 110) with a finger (Fig. 7F, ref. 110) received in a receptacle (Fig. 7F, ref. 354, left), said finger being movable from a location in said receptacle to a location projecting from said receptacle to removably

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engage said groove of said guide sleeve housing (Fig. 7F). The central distractor tip includes a reduced height configuration whereby said upper and lower distraction surfaces are orientable away from vertebral endplates of a spinal disc space and said finger is not engaged to said guide sleeve housing; and said central distractor tip is rotatable to a distraction configuration from said reduced height configuration whereby said upper and lower distraction surfaces are orientable toward vertebral endplates of a spinal disc space and said finger is actuated and received in said groove thereby coupling said guide sleeve housing to said central distractor (Fig. 7F, Fig. 7A). The guide sleeve housing is removably engageable to a housing inserter (Fig. 5), said housing inserter including a finger (Fig. 5, ref. 169), a shaft coupled to and extending proximally from said finger (Fig. 5, ref. 160), and an actuation handle coupled to a proximal end of said shaft (Fig. 5, proximal portion of ref. 162), said finger being movable with said actuation handle to removably engage said housing inserter to said guide sleeve housing (Fig. 5). The central distractor includes a shaft extending proximally from said distractor tip (Fig. 7F, ref. 102) and wherein said housing inserter and said guide sleeve housing are positionable over a proximal end of said shaft of said central distractor (Fig. 5) and movable to position said guide sleeve housing in an operative position adjacent the spinal disc space (Fig. 5). The central distractor is withdrawable from said guide sleeve housing (Fig. 7F). The instrument further comprises a guide sleeve (Fig. 5, ref. 146) engageable to said proximal portion of said guide sleeve housing. The first working channel port and said second working channel port of said guide sleeve housing are in communication with one another through said

guide sleeve housing (Fig. 7F). The guide sleeve housing includes a pair of lateral flanges (Fig. 7F, ref. 342) extending distally therefrom on opposite lateral sides of said guide sleeve housing. Each of said lateral flanges has a non-distracting height between upper and lower surfaces thereof (Fig. 7F, ref. 342). When in an operative position said proximal portion of said guide sleeve housing includes a first width transverse to the spinal column axis and said distal portion includes a second width transverse to the spinal column axis, said first width being greater than said second width and said central distractor extends distally from said distal portion (Fig. 7F, Fig. 7A).

Michelson discloses a spinal surgical instrument, comprising: a shaft (Fig. 7F, ref. 348), an engaging portion at a distal end of said shaft (Fig. 7F, towards ref. 344), wherein said member is a guide sleeve housing (Fig. 7F, ref. 344) defining first and second access ports (Fig. 7F, ports surrounding refs. 102) therethrough for accessing a spinal disc space with said engaging portion removed therefrom, said guide sleeve housing including a proximal portion (Fig. 7F, portion near ref. 344) defining a proximal chamber (Fig. 7F, chamber formed by the inner wall of ref. 344) and a distal portion defining said first and second access ports (Fig. 7F, near refs. 102, left and right) as a distal extension of said proximal chamber (Fig. 7F); a distractor tip (Fig. 7F, ref. 102) extending distally of said engaging portion (Fig. 7F), wherein said engaging portion has an enlarged configuration (Fig. 7F) and extends outwardly from each of said shaft and said distractor tip (Fig. 7F). The distractor tip is rotatable relative to said engaging portion between a distraction configuration and a reduced height configuration (Fig. 7F, Fig. 7A). The distractor tip includes an upper distracting surface and an opposite lower

distracting surface (Fig. 7A). At least one of said upper and lower distracting surfaces includes a vertebral endplate engaging surface (Fig. 7A). The distractor tip is rotatable relative to said engaging portion with said shaft (Fig. 7F), said distractor tip having a distraction configuration. The guide sleeve housing includes a pair of lateral flanges (Fig. 7F, ref. 342) extending distally therefrom on opposite lateral sides of said guide sleeve housing. Each of said lateral flanges has a non-distracting height between upper and lower surfaces thereof (Fig. 7F, ref. 342).

Michelson discloses a spinal instrument assembly, comprising: a guide sleeve housing (Fig. 7F, ref. 348) including a proximal portion and a distal portion (Fig. 7F), said proximal portion including an inner wall defining a proximal chamber (Fig. 7F, chamber formed by inner wall of ref. 100), said housing further including a first working channel port and a second working channel port (Fig. 7F, ports surrounding ref. 102, left and right) extending through said distal portion in communication with one another and in communication with said proximal chamber (Fig. 7F); and a central distractor (Fig. 7F, ref. 100) in said chamber of said guide sleeve housing, said central distractor including a distractor tip between said first and second working channel ports (Fig. 7F), said distractor tip including upper and lower distraction surfaces (Fig. 7A) defining a distraction height therebetween to maintain distraction of a spinal disc space (Fig. 7A). The proximal portion includes an overall width between opposite lateral sides thereof that is less than an overall width between opposite lateral sides of said distal portion of said guide sleeve housing (Fig. 7F), and further wherein said guide sleeve housing includes a lip (Fig. 7F, ref. 344) extending completely therearound at the junction

between said proximal portion and said distal portion to provide an external indication of the relative locations of the proximal and distal portions, and further wherein said central distractor extends distally from said distal portion (Fig. 7F). The central distractor is removable from said guide sleeve housing (Fig. 7F).

Michelson discloses the claimed invention except for portions of the device being releasably engageable with other portions of the device and the engagement mechanism comprising a finger and receptacle type engagement mechanism.

Initially, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have separated what can be considered to be the guide sleeve housing (namely ref. 344) from the guide sleeve, ref. 348), since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. Secondly, Michelson discloses connecting various instruments together using a flange and groove (*i.e.* a finger and receptacle), which is a well known technique used to connect instruments together (column 22, lines 6-11). Therefore, It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the guide sleeve housing and the engaging portion with a flange and receptacle type connection, since Michelson discloses that such a mechanism is well known in the art to connect instruments together.

Claims 1-6, 8-19 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US Pat. 5,505,732) in view of Ray (US Pat. 5,055,104).



Michelson does not disclose the ports together forming an oval shaped working channel port through said distal portion and the guide sleeve housing does not include a medial wall in said proximal chamber between first and second working channel ports. Michelson however does disclose ports being used to carry instruments into a vertebral space (column 52, lines 4-9).

Ray discloses a device (Fig. 9, ref. 80) with ports (Fig. 87, ref. 90)(column 6, lines 6-22) that are used to deliver instrumentation into a vertebral space (column 6, lines 6-22).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the ports of Ray with the ports of Michelson, in order to achieve the predictable result of providing ports to allow the delivery of instrumentation into a vertebral space. The ports would then form an oval shape (Fig. 8) and not have a medial wall separating them (Fig. 8).

### ***Response to Arguments***

Applicant's arguments filed 02/28/2008 have been fully considered but they are not persuasive.

With regard to Applicant's argument that there is no releasably engageable portion taught by Michelson, the examiner notes that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have separated what can be considered to be the guide sleeve housing (namely ref. 344) from the guide sleeve, ref. 348), since it has been held that constructing a formerly integral structure in

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various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. Michelson further teaches connection mechanisms that are common in the art, one of which, at least, can be considered to be a flange and groove connection mechanism (*i.e.* a finger and receptacle)(column 22, lines 6-11). Since it is obvious to separate portions of a device from one another as discussed in *Nerwin v. Erlichman* and Michelson further teaches that it is obvious to use a finger and receptacle type connection mechanism, it would have been obvious to one of ordinary skill in the art to have constructed the device with a releasably engageable portion that is connected with a flange and groove connection mechanism.

With regard to Applicant's argument directed toward "the enlarged configuration being sized and shaped to fit in the proximal chamber with a close interfit to provide a rigid assembly between said engaging portion and said guide sleeve housing" it is noted that the portion with the enlarged configuration, once separated from the device as described above, would be capable of being wedged or forced into at least a portion of the proximal chamber to create such a fit.

With regard to Applicant's arguments directed to the functioning of the fingers and the grooves, the examiner notes that he is treating these statements as functional recitations and that the Michelson device is capable of performing these functions when fingers and grooves as taught by Michelson are constructed in the device. The fingers would be capable of moving and the distractor tip could be used to manipulate the placement of the finger.

With regard to Applicant's argument that the device includes a medial wall separating the device, the examiner notes that near the end of the device there is at least a portion of ref. 80 (e.g. near ref. 86) that includes a substantially oval shape (Fig. 8).

With regard to Applicant's argument that the distractor is not located "in a location between the ports" the examiner notes initially that this phrase is located within a functional clause and the device must merely be capable of performing such a function. Secondly, the distractor can be considered to be "between" the ports. For example, referring to Fig. 7F, the distractor tips are located between the lateral most portions of the ports and can be considered to be located "between" the ports.

With regard to Applicant's arguments directed toward the finger projecting from the receptacle, the examiner notes that these claimed elements are recited functionally in claims 10 and 11 and the device of Michelson in view of Ray would be capable of placing the finger in such a way.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733